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EXAMINER	
MORGAN, ROBERT W	

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/556,945	MARKS, JAMES D.	
	Examiner	Art Unit	
	Robert W. Morgan	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *73-104 and 126-148* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *73-104 and 126-148* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/5/04 has been entered.

Response to Amendment

2. In the amendment filed 1/7/04 in paper number 10, the following has occurred: Claims 1-2, 15, 19-21, 25-26, 31, 34-41, 44-50, 53-57, 59, 61-64, 67, 69-70, 73-75, 77, 79-80, 82-90, 92, 94-98, 100, 102-104, 131-132, 134-136, 138-139, 141, 143-144 and 147 have been amended. Claims 105-125 have been canceled and claim 149 has been added. Now claims 73-104 and 126-149 are presented for examination.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 73-74, 92, 96, 102-104, 130-143, 146 and 149 and are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,991,731 to Colon et al. in view of "drkoop.com & Quintiles Launch Service to Recruit Clinical Trial Patient on the Internet" by PR Newswire (hereafter "Newswire").

As per claim 73, Colon et al. teaches an Internet-networked system with online communication to a computing center from a large number of clinical study investigators at numerous and diverse locations remote from the computing center (see: column 1, lines 36-38). In additions, the system handles automatic assignment and randomization of thousands of participants in a clinical study with respect to care strategies to be administered to the study participants (see: column 1, lines 48-51). Furthermore, the system captures data in its database through appropriate input forms developed for the specific clinical study and the data is stored online and reports are produced in real time to study investigators and to the sponsor regarding sites that are participating, recruitment levels by participating site, patient follow-up, and significant events (see: column 1, lines 64 to column 2, lines 4). Additionally, Colon et al. teaches computer system (17, 18, 19, Fig. 1) with a screen that brings up a form used for entering patient related data such as identification, demographics and medical conditions and later transmitted to the study management center (10, Fig. 1) as represented by input block (61, Fig. 5) (see: column 6, lines 22-30).

Colon fails to teach electronic consent to an agreement volunteering for consideration as a potential candidate for potential the clinical trials and adding the at least one of the individual's medical information and personally identifying information to a database of at least one individual available for consideration as a potential candidate for the clinical trials.

Newswire teaches a customer Internet resource to enable interested individuals to sign up on-line for possible participation in clinical trials via a web site (see: paragraph 1). Newswire further teaches interested individuals who do not fit a trial's inclusion criteria will receive other useful information, and can consent to having their pre-screening information stored in a

database and matched with the appropriate trial in the future (see: paragraph 12). In addition, Newswire teaches that no individual information is stored in or transferred from the database without the individual's consent (see: paragraph 10).

One of ordinary skill in art at the time the invention was made would have found it obvious to include the online individual consent as taught by Newswire within the method for managing data used in conducting clinical studies as taught by Colon et al. with the motivation of increasing the efficiency and speed of the clinical trials process (see: paragraph 6).

As per claim 74, Newswire teaches the claimed clinical trials include one of a plurality of potential clinical trials, plurality of clinical trials in progress and a potential clinical trial and a clinical trial in process. This limitation is met by the www.drkoop.com/hcr/trials that offers access information about a number of ongoing studies (see: paragraph 9).

As per claim 92, Colon et al., Newswire and Clark et al. teach the claimed generating a certificate to verify transmission between the individual and secure server. This limitation is met by the patient being asked sign an informed consent electronically and acknowledge of the consent is printed (see: Clark et al.: column 4, lines 19-22). In addition, Colon et al. and Clark et al. teach the use of Internet server (13, Fig. 1) used to provide Internet network service to all authorized users (see: Colon et al.: column 3, lines 24-44).

As per claim 96, Newswire teaches:

--the claimed receiving from the individual an opt-out request and at least one opt-out identification information, the opt-out identification information being used to authenticate the request is met by the individual withdrawing their consent from participating in the clinical trial and requires that their personal information be removed from the database at any time (see:

paragraph 12). The Examiner considers that once an user has logon to the system, any information being used is considered authenticated or equivalent to an authentication request for user identification; and

--the claimed removing the at least one of the individual's medical information and personally identifying information from the database, whereby the individual is remove from consideration as a potential candidate for the clinical trials is met by the individual withdrawing their consent from participating in the clinical trial and requires that their personal information be removed from the database at any time (see: paragraph 12).

As per claim 102, Colon et al. and Newswire teach the claimed secure server generates an electronic opt-out form to be displayed on the computer terminal and further comprising receiving the opt-out request on the electronic opt-out form. This limitation is met by the eligibility routine, where an determination is made at the time when patient data is submitted, whether the patient qualifies for the clinical study, and if not, a message is communicated to the clinical study investigator's computer (see: Colon et al.: column 2, lines 5-9). In addition, Colon et al. and Newswire teach the use of Internet server (13, Fig. 1) used to provide Internet network service to all authorized users (see: Colon et al.: column 3, lines 24-44). Furthermore, Colon et al. and Newswire further teach an individual withdrawing their consent from participating in the clinical trial and require that their personal information be removed from the database at any time (see: Newswire: paragraph 12).

As per claims 103 and 104, they are rejected for the same reasons set forth in claim 74.

As per claims 130, 137 and 140, Colon et al., Newswire and Clark et al. teach the claimed personally identifying information comprises one of name, address, telephone number, e-mail

address and name with birth date and the medical information comprises medical data relevant to being selected as a candidate for one of a potential clinical trial and a clinical trial in progress. This limitation is met by the method and apparatus for authenticating informed consent for patient that includes providing a means for the patient to input data in the form of answers to questions as well as prompting the patient for electronic signature (see: Clark: column 11, lines 66 to column 12, lines 50). The Examiner considers using a name for the electronic signature, which is unique to each person, as example of personally identifying information. In addition, Colon et al., Newswire and Clark et al. teach computer system (17, 18, 19, Fig. 1) with a screen that brings up a form used for entering patient related data such as identification, demographics and medical conditions and later transmitted to the study management center (10, Fig. 1) as represented by input block (61, Fig. 5) (see: Colon et al.: column 6, lines 22-30).

As per claim 131, Colon et al. teaches an Internet-networked system with online communication to a computing center from a large number of clinical study investigators at numerous and diverse locations remote from the computing center (see: column 1, lines 36-38). In additions, the system handles automatic assignment and randomization of thousands of participants in a clinical study with respect to care strategies to be administered to the study participants (see: column 1, lines 48-51). Furthermore, the system captures data in its database through appropriate input forms developed for the specific clinical study and the data is stored online and reports are produced in real time to study investigators and to the sponsor regarding sites that are participating, recruitment levels by participating site, patient follow-up, and significant events (see: column 1, lines 64 to column 2, lines 4). Additionally, Colon et al. teaches computer system (17, 18, 19, Fig. 1) with a screen that brings up a form used for entering

patient related data such as identification, demographics and medical conditions and later transmitted to the study management center (10, Fig. 1) as represented by input block (61, Fig. 5) (see: column 6, lines 22-30).

Colon et al. fails to teach the claimed electronic consent to an agreement volunteering for consideration as a member of a pool of potential candidates for review and selection for the clinical trials and adding the at least one of the individual's information to a database of at least one individual available for consideration as a potential candidate for the clinical trials.

Newswire teaches a customer Internet resource to enable interested individuals to sign up on-line for possible participation in clinical trials via a web site (see: paragraph 1). Newswire further teaches interested individuals who do not fit a trial's inclusion criteria will receive other useful information, and can consent to having their pre-screening information stored in a database and matched with the appropriate trial in the future (see: paragraph 12). In addition, Newswire teaches that no individual information is stored in or transferred from the database without the individual's consent (see: paragraph 10).

The obviousness of combining the teachings of Newswire within Colon et al. has been discussed in the rejection of claim 73, and incorporated herein.

As per claim 132 and 141, Colon et al. teaches a computer system (17, 18, 19, Fig. 1) (reads on "enrollment interface and plurality of remote computer terminals") with a screen that brings up a form used for entering patient related data such as identification, demographics and medical conditions and later transmitted to the study management center (10, Fig. 1) as represented by input block (61, Fig. 5) (see: column 6, lines 22-30). Colon et al. further teaches the use of Internet server (13, Fig. 1) used to provide Internet network service to all authorized

users (see: column 3, lines 24-44). Additionally, Colon et al. teaches computer system (17, 18, 19, Fig. 1) with a screen that brings up a form used for entering patient related data such as identification, demographics and medical conditions and later transmitted to the study management center (10, Fig. 1) as represented by input block (61, Fig. 5) (see: column 6, lines 22-30).

Colon et al. fails to teach receiving electronic consent to the agreement and adding at least one piece of medical information to a database of individuals available for enrollment in the clinical trails.

Newswire teaches a customer Internet resource to enable interested individuals to sign up on-line for possible participation in clinical trials via a web site and the final decision to participate requires the patient's informed consent (see: paragraph 1 and 10). Newswire further teaches interested individuals who do not fit a trial's inclusion criteria will receive other useful information, and can consent to having their pre-screening information stored in a database and matched with the appropriate trial in the future (see: paragraph 12). In addition, Newswire teaches that no individual information is stored in or transferred from the database without the individual's consent (see: paragraph 10).

The obviousness of combining the teachings of Newswire within Colon et al. has been discussed in the rejection of claim 73, and incorporated herein.

As per claims 133, 142 and 146 Colon et al. teaches the claimed computer network is one of an Internet, world wide web, intranet, local area network, wide area network, and wireless communication network. This limitation is met by the remote computers (17, 18, 19, Fig. 1)

connected through modems (20, 21, 22, Fig. 1) to the Internet (17, Fig. 1) (see: column 3, lines 9-10).

As per claim 134, Colon et al. teaches an Internet-networked system with online communication to a computing center from a large number of clinical study investigators at numerous and diverse locations remote from the computing center (see: column 1, lines 36-38). In additions, the system handles automatic assignment and randomization of thousands of participants in a clinical study with respect to care strategies to be administered to the study participants (see: column 1, lines 48-51). Furthermore, the system captures data in its database through appropriate input forms developed for the specific clinical study and the data is stored online and reports are produced in real time to study investigators and to the sponsor regarding sites that are participating, recruitment levels by participating site, patient follow-up, and significant events (see: column 1, lines 64 to column 2, lines 4). Additionally, Colon et al. teaches a computer system (17, 18, 19, Fig. 1) with a screen that brings up a form used for entering patient related data such as identification, demographics and medical conditions and later transmitted to the study management center (10, Fig. 1) as represented by input block (61, Fig. 5) (see: column 6, lines 22-30).

Colon et al. fails to teach the claimed electronic consent by an individual at a computer terminal for consideration as a potential candidate for the clinical trials and adding at least one piece of information for the individual to a database of at least one individual available for consideration as a potential candidate for the clinical trials.

Newswire teaches a customer Internet resource to enable interested individuals to sign up on-line for possible participation in clinical trials via a web site and the final decision to

participate requires the patient's informed consent (see: paragraph 1 and 10). Newswire further teaches interested individuals who do not fit a trial's inclusion criteria will receive other useful information, and can consent to having their pre-screening information stored in a database and matched with the appropriate trial in the future (see: paragraph 12). In addition, Newswire teaches that no individual information is stored in or transferred from the database without the individual's consent (see: paragraph 10).

The obviousness of combining the teachings of Newswire within Colon et al. has been discussed in the rejection of claim 73, and incorporated herein.

As per claims 135, it is rejected for the same reasons set forth in claim 74.

As per claim 136, Colon et al. and Newswire teaches a computer system (17, 18, 19, Fig. 1) with a screen that brings up a form used for entering patient related data such as identification, demographics and medical conditions and later transmitted to the study management center (10, Fig. 1) as represented by input block (61, Fig. 5) (see: Colon et al.: column 6, lines 22-30). In addition, Colon et al. and Newswire teach in order to protect privacy, personally identifiable information will only be disclosed with individual 's permission and only to help them participate in a clinical trial (see: Newswire: paragraph 12).

As per claim 138, Colon et al. teaches the use of Internet server (13, Fig. 1) used to provide Internet network service to all authorized users (see: Colon et al.: column 3, lines 24-44). Colon et al. teaches an Internet-networked system with online communication to a computing center from a large number of clinical study investigators at numerous and diverse locations remote from the computing center (see: column 1, lines 36-38). In additions, the system handles automatic assignment and randomization of thousands of participants in a clinical study with

respect to care strategies to be administered to the study participants (see: column 1, lines 48-51). Furthermore, the system captures data in its database through appropriate input forms developed for the specific clinical study and the data is stored online and reports are produced in real time to study investigators and to the sponsor regarding sites that are participating, recruitment levels by participating site, patient follow-up, and significant events (see: column 1, lines 64 to column 2, lines 4). Additionally, Colon et al. teaches computer system (17, 18, 19, Fig. 1) with a screen that brings up a form used for entering patient related data such as identification, demographics and medical conditions and later transmitted to the study management center (10, Fig. 1) as represented by input block (61, Fig. 5) (see: column 6, lines 22-30).

Colon et al. fail to teach the claimed providing consent to said agreement in order to volunteer for consideration as a potential candidate for the clinical trials and adding at least one piece of information for the individual to a database of individuals available for consideration as a potential candidate for the clinical trials.

Newswire teaches a customer Internet resource to enable interested individuals to sign up on-line for possible participation in clinical trials via a web site (see: paragraph 1). Newswire further teaches interested individuals who do not fit a trial's inclusion criteria will receive other useful information, and can consent to having their pre-screening information stored in a database and matched with the appropriate trial in the future (see: paragraph 12). In addition, Newswire teaches that no individual information is stored in or transferred from the database without the individual's consent (see: paragraph 10).

The obviousness of combining the teachings of Newswire within Colon et al. has been discussed in the rejection of claim 73, and incorporated herein.

As per claim 139, Colon et al. and Newswire teach the claimed agreement further relates to the release of at least one of medical and personally identifying information and wherein said at least one computer terminal is further used by the individual to provide consent to said agreement including the release of the information to an administrator of one of the clinical trials. This limitation is met by protecting privacy; personally identifiable information will only be disclosed with individual 's permission and only to help them participate in a clinical trial (see: Newswire: paragraph 12). In addition, Colon et al. and Newswire teach a computer system (17, 18, 19, Fig. 1) with a screen that brings up a form used for entering patient related data such as identification, demographics and medical conditions and later transmitted to the study management center (10, Fig. 1) as represented by input block (61, Fig. 5) (see: Colon et al.: column 6, lines 22-30).

As per claim 143, Colon et al. teaches a study management center (10, Fig. 1) at a particular geographical site that includes a database host computer (11, Fig. 1) connected via network (12, Fig. 1) to an Internet server (13, Fig. 1) (see: column 2, lines 58-64). In addition, Colon et al. further teaches a system that captures data in its database through appropriate input forms developed for the specific clinical study and the data is stored online and reports are produced in real time to study investigators and to the sponsor regarding sites that are participating, recruitment levels by participating site, patient follow-up, and significant events (see: column 1, lines 64 to column 2, lines 4). Additionally, Colon et al. teaches computer system (17, 18, 19, Fig. 1) with a screen that brings up a form used for entering patient related data such as identification, demographics and medical conditions and later transmitted to the study

management center (10, Fig. 1) as represented by input block (61, Fig. 5) (see: column 6, lines 22-30).

Colon et al. fails to teaches the claimed records include at least one piece of personally identifying information about the individual and corresponding to the individual's electronic consent to volunteer as a potential candidate for the clinical trial provided by the individual by routing an acceptance of an agreement over a computer network.

Newswire teaches a customer Internet resource to enable interested individuals to sign up on-line for possible participation in clinical trials via a web site (see: paragraph 1). Newswire further teaches interested individuals who do not fit a trial's inclusion criteria will receive other useful information, and can consent to have their pre-screening information stored in a database and matched with appropriate trial in the future (see: paragraph 12). In addition, Newswire teaches that no individual information is stored in or transferred from the database without the individual's consent (see: paragraph 10). Additionally, Newswire teaches that in order to protect privacy, personally identifiable information will only be disclosed with individual 's permission and only to help them participate in a clinical trial (see: Newswire: paragraph 12).

The obviousness of combining the teachings of Newswire within Colon et al. has been discussed in the rejection of claim 73, and incorporated herein.

As per claim 149, Newswire teaches:

--the claimed receiving over the network an opt-out request to remove an individual's one of medical information and personally identifying information from the database is met by the individual withdrawing their consent from participating in the clinical trial and requires that their personal information be removed from the database at any time (see: paragraph 12); and

--the claimed removing the information from the database, whereby the individual is removed from consideration for recruitment is met by the individual withdrawing their consent from participating in the clinical trial and requires that their personal information be removed from the database at any time (see: paragraph 12).

5. Claims 75-91, 93-95, 144 and 145 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,991,731 to Colon et al. and "drkoop.com & Quintiles Launch Service to Recruit Clinical Trial Patient on the Internet" by PR Newswire (hereafter "Newswire") as applied to claim 73 above, and further in view of U.S. Patent No. 6,171,112 to Clark et al.

As per claim 75, Colon et al. and Newswire teach a customer Internet resource to enable interested individuals to sign up on-line for possible participation in clinical trials via a web site and final decision to participate requires the patient's informed consent (see: Newswire: paragraph 1 and 10).

Colon et al. and Newswire fail to explicitly teach the claimed agreement is a click wrap consent agreement.

Clark et al. teaches a method and apparatus for authenticating informed consent for patient that includes providing a means for the patient to input data in the form of answers to questions as well as prompting the patient for electronic signature (see: column 11, lines 66 to column 12, lines 50 and Fig. 17).

One of ordinary skill in the art at the time the invention was made would have found it obvious to include authenticating informed consent for patient as taught by Clark et al. with the system as taught by Colon et al. and Newswire with the motivation of positively affecting the

patient-physician relationship by allowing the physician to accomplish more with each patient in less time (see: Clark et al.: column 3, lines 37-40).

As per claim 76, Clark et al. teaches the claimed generating an electronic survey form to be displayed at the computer terminal. This limitation is met by the computer system (17, 18, 19, Fig. 1) with a screen that brings up a form used for entering patient related data (see: column 6, lines 22-30).

As per claim 77, Clark et al. teaches the claimed displaying the electronic survey form in response to receipt of the individual's consent to the agreement. This limitation is met by an individual seeking informed consent and selecting the appropriate survey that requires authentication of the recipient's (see: column 6, lines 33-36).

As per claim 78, Colon et al. teaches the claimed electronic survey form comprises at least one of information and medical related questions. This feature is met by the computer system (17, 18, 19, Fig. 1) with a screen that brings up a form used for entering patient related data such as identification, demographics and medical conditions and later transmitted to the study management center (10, Fig. 1) as represented by input block (61, Fig. 5) (see: column 6, lines 22-30).

As per claims 79-81, Colon et al., Newswire and Clark et al. teach a computer system (17, 18, 19, Fig. 1) with a screen that brings up a form used for entering patient related data such as identification, demographics and medical conditions and later transmitted to the study management center (10, Fig. 1) as represented by input block (61, Fig. 5) (see: Colon et al. column 6, lines 22-30). Colon et al and Clark et al. method of obtaining an informed patient consent during a patient session, which includes the answering of questions by the patient and

this data is encrypted and transmitted to a central data facility (see: Clark et al.: column 4, lines 31-55). In addition, the data maybe transferred via the Internet, a dedicated local area network, leased private or semi-private data transmission lines using encryption or other secure means (see: Clark et al.: column 10, lines 54-57). Furthermore, Colon et al. and Clark et al. teach the use of Internet server (13, Fig. 1) used to provide Internet network service to all authorized users (see: Colon et al.: column 3, lines 24-44).

As per claims 82-89, Colon et al., Newswire and Clark et al. teach the use of Internet server (13, Fig. 1) used to provide Internet network service to all authorized users (see: Colon et al.: column 3, lines 24-44). Colon et al., Newswire and Clark et al. also teach a method and apparatus for authenticating informed consent where transferred patient data (706, Fig. 7) is recorded and stored securely at the data facility (702, Fig. 7) using encryption technology. The encryption ensures maximum protection of patient privacy and the security of the network. Encryption is done using standard private/public key system and a decryption key used to restore the encrypted data to original form (see: Clark et al.: column 17, lines 1-18). Colon et al., Newswire and Clark et al. further teach that transferred data from the data facility (702, Fig. 7) to the Virtual Interactive Teaching and Learning (VITAL) Centers is updated to ensure that the information is up-to-date and accurate (see: Clark et al.: column 17, lines 26-30 and Fig. 9). Colon et al., Newswire and Clark et al. also teach that only authorized personnel can access the system to protect the integrity of system by minimizing the chance of intentional or inadvertent corruption of patient information (see: Clark et al.: column 12, lines 58-61). The Examiner considers the authorized personnel accessing the system as the only users providing requests and responses to retrieve data from the memory devices.

As per claim 90, Colon et al., Newswire and Clark et al. teach the claimed authorized individual reviews the encrypted processed data and select the individual as a potential candidate is met by the only authorized personnel accessing the system to protect the integrity of system by minimizing the chance of intentional or inadvertent corruption of patient information (see: Clark et al.: column 12, lines 58-61), the method comprising:

--the claimed communicating to individual the selection as the potential candidate is met by the user table (48, Fig. 4) that contains contact information related to the user (see: Colon et al.: column 5, lines 17-20).

As per claim 91, Colon teaches the claimed communication comprises one of:

(d) the central office contacting the potential candidate in order to request permission for the authorized individual to contact the potential candidate;

(e) the central office providing the authorized individual with contact information for the potential candidate and the authorized individual communicating with the potential candidate; and

(f) the central office communicating to the potential candidate the selection and providing contact information for the potential candidate to initiate contact with the one of the authorized individual and an employee of the clinical trial associated with the authorized individual.

Colon et al. teach the claimed (e) the central office providing the authorized individual with contact information for the potential candidate and the authorized individual communicating with the potential candidate. This limitation is met by the user table (48, Fig. 4) that contains contact information related to the user (see: column 5, lines 17-20). In addition, Colon et al. teaches a permission table (49, Fig. 4) that contains flags that are used to authorize a

user for access to information about sites, regions and study level information (see: column 5, lines 17-25).

As per claim 93, Colon et al. teaches the claimed computer terminal employs a web browser capable of supporting a secure socket layer protocol (see: column 3, lines 39-41).

As per claim 94, Colon et al., Newswire and Clark et al. teach the claimed ensuring that decrypted information stored at said secure server is not accessed by unauthorized personnel. This feature is met by the method and apparatus for authenticating informed consent where transferred patient data (706, Fig. 7) is recorded and stored securely at the data facility (702, Fig. 7) using encryption technology. The encryption ensures maximum protection of patient privacy and the security of the network. Encryption is done using standard private/public key system and a decryption key used to restore the encrypted data to original form (see: Clark et al.: column 17, lines 1-18). Clark et al. also teaches that only authorized personnel can access the system to protect the integrity of system by minimizing the chance of intentional or inadvertent corruption of patient information (see: Clark et al.: column 12, lines 58-61). In addition, Colon et al. and Clark et al. teach the use of Internet server (13, Fig. 1) used to provide Internet network service to all authorized users (see: Colon et al.: column 3, lines 24-44).

As per claim 95, Colon et al. and Clark et al. teaches the claimed ensuring step comprises at least one of limiting access to said secure server to a minimum number of authorized personnel and devising and implementing procedures to ensure that only authorized personnel gain access to the decrypted data. This feature is met by allowing only authorized personnel to access the system to protect the integrity of system by minimizing the chance of intentional or inadvertent corruption of patient information (see: Clark et al.: column 12, lines 58-61). In

addition, Colon et al. and Clark et al. teach the use of Internet server (13, Fig. 1) used to provide Internet network service to all authorized users (see: Colon et al.: column 3, lines 24-44).

As per claim 144, Colon et al. and Newswire teach a system that captures data in its database through appropriate input forms developed for the specific clinical study and the data is stored online and reports are produced in real time to study investigators and to the sponsor regarding sites that are participating, recruitment levels by participating site, patient follow-up, and significant events (see: column 1, lines 64 to column 2, lines 4). In addition, Colon et al. and Newswire teach interested individuals who do not fit a trial's inclusion criteria will receive other useful information, and can consent to have their pre-screening information stored in a database and matched with appropriate trial in the future (see: paragraph 12).

Colon et al. and Newswire fail to teach the claimed acceptance of the agreement is generated based on the agreement being displayed at a computer terminal and the individual providing an acceptance to the agreement at the computer terminal.

Clark et al. teaches a method and apparatus for authenticating informed consent for patient that includes providing a means for the patient to input data in the form of answers to questions as well as prompting the patient for electronic signature (see: column 11, lines 66 to column 12, lines 50 and Fig. 17).

The obviousness of combining the teachings of Clark et al. with the system of Colon et al. and Newswire has been discussed in the rejection of claim 75, and incorporated herein.

As per claim 145, Colon et al. and Newswire fail to teach the claimed medical information is generated based on a health survey being displayed at a computer terminal and the individual providing the information as input at the computer terminal.

Clark et al. teaches a method and apparatus for authenticating informed consent for patient that includes providing a means for the patient to input data in the form of answers to questions as well as prompting the patient for electronic signature (see: column 11, lines 66 to column 12, lines 50 and Fig. 17).

The obviousness of combining the teachings of Clark et al. with the system of Colon et al. and Newswire are discussed in rejection of claim 75, and incorporated herein.

6. Claim 97 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,991,731 to Colon et al. and "drkoop.com & Quintiles Launch Service to Recruit Clinical Trial Patient on the Internet" by PR Newswire (hereafter "Newswire") as applied to claim 73 above, and further in view of Official Notice.

As per claim 97, Colon et al. and Newswire fail to teach the claimed agreement satisfies all federal, state, and local rules, ordinances and regulations.

However, it is well known in the computer field that electronic agreements or contracts use and follow all federal, state, and local rules, ordinances and regulations with regard to the dissemination of medical, health and personally identifying information. Therefore, it would have been obvious a person of ordinary skill in the art at the time the invention was made to include an electronic agreement that satisfies all federal, state, and local rules, ordinances and regulations with regard to the dissemination of medical, health and personally identifying information with the combined system of Colon et al. and Newswire with the motivation of avoiding the any negligent and malpractice litigation caused by not stating and following all federal, state, and local rules, ordinances and regulations.

7. Claims 98-99 and 126-127 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,991,731 to Colon et al., "drkoop.com & Quintiles Launch Service to Recruit Clinical Trial Patient on the Internet" by PR Newswire (hereafter "Newswire") and U.S. Patent No. 6,171,112 to Clark et al. as applied to claims 73 and 85 above and in view of U.S. Patent No. 6,272,470 to Teshima.

As per claims 98-99, Colon et al., Newswire and Clark et al. teach method and apparatus for authenticating informed consent where transferred patient data (706, Fig. 7) is recorded and stored securely at the data facility (702, Fig. 7) using encryption technology. The encryption ensures maximum protection of patient privacy and the security of the network. Encryption is done using standard private/public key system and a decryption key used to restore the encrypted data to original form (see: Clark et al.: column 17, lines 1-18).

Colon et al., Newswire and Clark et al. fail to explicitly teach shareware encryption protocol that is Pretty Good Privacy.

Teshima teaches an electronic clinical recording system that includes encrypting/decrypting software referred to as PGP (Pretty Good Privacy) using public keys (see: column 15, lines 34-41).

One of ordinary skill in the art at the time the invention was made would have found it obvious to include encrypting/decrypting software such as PGP (Pretty Good Privacy) as taught by Teshima with the system of Colon et al., Newswire and Clark et al. with the motivation of preventing unauthorized access to valuable data thereby ensuring the privacy and security of the information.

As per claims 126-127, they are rejected for the same reasons set forth in claims 98-99.

8. Claims 100-101 and 128-129 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,991,731 to Colon et al. and "drkoop.com & Quintiles Launch Service to Recruit Clinical Trial Patient on the Internet" by PR Newswire (hereafter "Newswire") and U.S. Patent No. 6,171,112 to Clark et al. as applied to claim 89 above, and further in view of Official Notice.

As per claim 100, Colon et al., Newswire and Clark et al. fail to explicitly teach the claimed decryption of the retrieved encrypted information from the second memory device is performed using encryption keys stored on a disk kept under physical surveillance.

However, Colon et al., Newswire and Clark et al. teach method and apparatus for authenticating informed consent where transferred patient data (706, Fig. 7) is recorded and stored securely at the data facility (702, Fig. 7) using encryption technology. The encryption ensures maximum protection of patient privacy and the security of the network. Encryption is done using standard private/public key system and a decryption key used to restore the encrypted data to original form (see: Clark et al.: column 17, lines 1-18). It is well known in the computer industry for a person to be possession of a disk used to store standard private/public encryption and decryption keys as described by Colon et al., Newswire and Clark et al. Therefore, it would have been obvious to a person of ordinary skill in the art the time the invention was made to include storing a encryption keys on a disk kept under physical surveillance with in the system of Colon et al., Newswire and Clark et al. with the motivation of preventing unauthorized access to valuable data thereby ensuring the privacy and security of the information.

As per claim 101, Clark et al. teaches the claimed personally identifying information is one of name, address, telephone number, e-mail address and name with birth date. This

limitation is met by the method and apparatus for authenticating informed consent for patient that includes providing a means for the patient to input data in the form of answers to questions as well as prompting the patient for electronic signature (see: column 11, lines 66 to column 12, lines 50). The Examiner considers using a name for the electronic signature, which is unique to each person, as example of personally identifying information.

As per claims 128-129, they are rejected for the same reasons set forth in claims 100-101.

9. Claim 147 is rejected under 35 U.S.C. 103(a) as being unpatentable over "drkoop.com & Quintiles Launch Service to Recruit Clinical Trial Patient on the Internet" by PR Newswire (hereafter "Newswire") in view of U.S. Patent No. 6,171,112 to Clark et al.

As per claim 147, Newswire teaches interactive questionnaires to pre-screen potential participants where individual's responses are evaluated to determine if they meet the clinical trial basic criteria (see: paragraph 10). In addition, Newswire teaches www.drkoop.com/hcr/trials that offers access information about a number of ongoing studies, including a summary of the trial, inclusion and exclusion criteria (see: paragraph 9). Newswire further teaches that interested individuals can consent to have their pre-screening information stored in a database and matched with appropriate clinical trials in the future (see: paragraph 12).

Newswire fails teaches on-line electronic consent to an agreement volunteering as a potential candidate for the clinical trial.

Clark et al. teaches a method and apparatus for authenticating informed consent for patient that includes providing a means for the patient to input data in the form of answers to questions as well as prompting the patient for electronic signature (see: column 11, lines 66 to column 12, lines 50 and Fig. 17).

One of ordinary skill in the art at the time the invention was made would have found it obvious to include authenticating informed consent for patient as taught by Clark et al. with the online individual consent as taught by Newswire with the motivation of positively affecting the patient-physician relationship by allowing the physician to accomplish more with each patient in less time (see: Clark et al.: column 3, lines 37-40).

10. Claim 148 is rejected under 35 U.S.C. 103(a) as being unpatentable over "drkoop.com & Quintiles Launch Service to Recruit Clinical Trial Patient on the Internet" by PR Newswire (hereafter "Newswire") and U.S. Patent No. 6,171,112 to Clark et al. further in view of U.S. Patent No. 5,991,731 to Colon et al.

As per claim 148, Newswire and Clark et al. fail to teach the claimed contacting the individual corresponding to the potential candidate record, which matches the criterion to request that the individual participate in the clinical trial.

Colon et al. teaches a user table (48, Fig. 4) that contains contact information related to the user (see: Colon et al.: column 5, lines 17-20).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include contact information as taught by Colon with system as taught by Newswire and Clark et al. with the motivation of providing each clinical study with personal information regarding the participants to allow for notification of any matches with a relevant clinical study.

Response to Arguments

11. Applicant's arguments filed 3/30/04 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 3/30/04.

(A) In the remarks the Applicant argues in substance that, (1) Colon et al., Clark et al. and Teshima fail to teach the amended features of medical and personally identifying information about the individual to a database of recruits/volunteer or a database including such information; and (2) Colon et al., Clark et al. and Teshima fail to teach the amended feature directed to analyzing information in a database. In response to Applicant arguments, it is respectfully submits that the Examiner has applied new prior art to the new and amended features of claims 73, 131, 132, 134, 138, 141, 143 and 147 at the present time. As such, Applicant's remarks with regard to the combination of Colon et al., Clark et al. and/or Teshima alone to the new and amended claims are moot in light of the new grounds of rejection given in the above Office Action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert W. Morgan whose telephone number is (703) 605-4441. The examiner can normally be reached on 8:30 a.m. - 5:00 p.m. Mon - Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (703) 305-9588. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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